



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Attorney Docket No.: 108306-00034

Räsänen et al.

Confirmation No. 4756

Application Serial No. 10/731,626

Examiner: Kwon, Brian Yong S.

Filing Date: December 9, 2003

Art Unit: 1614

For METHODS FOR THE TREATMENT AND PREVENTION OF PANCREATITIS AND FOR INDUCTION OF LIVER REGENERATION

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir.

We, Tilna-Liisa RÄSÄNEN, Leena ALHONEN, Riitta SINERVIRTA, Tuomo KEINÄNEN, Karl-Heinz HERZIG, Alex Radii KHOMUTOV, Jouko VEPSÄLÄINEN, and Juhani JÄNNE, hereby declare as follows:

- We are the co-inventors of the above-identified patent application.
- 2. The above-identified patent application relates to methods of treating pancreatitis including administering to a patient an effective amount of a compound of formula (I):

$$\begin{array}{c|c} R_2R_1N - (CR_3R_4)_a - N - (CR_5R_6)_b - N - (CR_7R_6)_c - N - R_9 \\ R_{10} & R_{11} & R_{12} & n \end{array}$$

wherein: each of a, b and c is an integer from 2 to about 8; n is an integer 0 or 1; and each of R_1 , R_2 , R_3 , R_4 , R_5 , R_6 , R_7 , R_8 , R_8 , R_{10} , R_{11} and R_{12} are, independently, hydrogen

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or alkyl of 1 to about 6 carbons; with the proviso that when n is 0, at least one of R_3 , R_4 , R_5 , and R_6 is alkyl of 1 to about 6 carbons, and when n is 1, at least one of R_3 , R_4 , R_5 , R_6 , R_7 and R_8 is alkyl of 1 to about 6 carbons.

- 3. The above-identified patent application further relates to methods of treating pancreatitis including administering to a patient an effective amount of a polyamine hydrocarbon analogue of spermidine.
- 4. The above-identified patent application also relates to methods of treating pancreatitis including administering to a patient an alkylated analog of spermidine selected from the group consisting of methylspermidine, 1-methylspermidine, α-methylspermidine, and N¹-acetylspermidine.
- 5. We are the co-authors of an article published in the *Journal of Biological Chemistry*, Volume 277, No. 42, pages 39867-39872, August 2002, and we are the co-inventors of the subject matter which is disclosed in said publication, and disclosed and claimed in the above-identified application, as set forth in paragraphs 2-4, *supra*.
- 6. The other co-author of the publication, Suvikki SUPPOLA, is not a co-inventor of the subject matter disclosed and claimed in the above-identified application, as set forth in paragraphs 2-4, *supra*.
- 7. We hereby declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true; and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Date: 0cf 24,2006

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